Exhibit C

LEXSEE 2004 U.S. DIST. LEXIS 11930

TORPHARM, INC., APOTEX CORP. and APOTEX, INC., Plaintiffs, v. PFIZER INC. and WARNER LAMBERT COMPANY (n/k/a WARNER-LAMBERT LLC), Defendants.

Civ. No. 03-990-SLR

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2004 U.S. Dist. LEXIS 11930

June 28, 2004, Decided

SUBSEQUENT HISTORY: Vacated by, Remanded by *Apotex Inc. v. Pfizer Inc., 2005 U.S. App. LEXIS 5930 (Fed. Cir., Apr. 11, 2005)*

DISPOSITION: **[*1]** Defendants' motions to dismiss granted.

LexisNexis(R) Headnotes

COUNSEL: Steven J. Balick, Esquire, John G. Day, Esquire, Ashby & Geddes, Wilmington, Delaware. Counsel for Plaintiffs. Of Counsel: William A. Rakoczy, Esquire, Paul J. Molino, Esquire, Deanne M. Mazzochi, Esquire, Matthew O. Brady, Esquire, Lord Bissell & Brook LLP, Chicago, Illinois.

Jack B. Blumenfeld, Esquire, James W. Parrett, Esquire, Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Dimitrios T. Drivas, Esquire, Jeffrey J. Oelke, Esquire, Adam Gahtan, Esquire, Brendan G. Woodard, Esquire, White & Case LLP, New York, New York.

JUDGES: Sue L. Robinson, United States District Judge.

OPINIONBY: Sue L. Robinson

OPINION:

MEMORANDUM OPINION

Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On October 29, 2003, plaintiffs TorPharm, Inc., Apotex Corp., and Apotex, Inc. filed a declaratory judgment action against defendants Pfizer Inc. and Warner-Lambert Company. Plaintiffs seek a declaration that their generic version of Pfizer's patented drug Accupril(R) will not infringe *U.S. Patent No. 4,743,450* ("the '450 patent"). (D.I. 1) On February 23, 2004, plaintiffs filed an **[*2]** amended complaint to provide additional information about the statutory scheme for the approval of generic drugs. (D.I. 18)

Plaintiff TorPharm is incorporated under the laws of Canada with its principal place of business in Etobicoke, Ontario, Canada. (D.I. 1 at P 5) TorPharm develops, manufactures, and markets generic drugs, in particular solid oral dosage forms, such as capsules and tablets, for sale and use in the United States. (Id.) Plaintiff Apotex Corp. is incorporated under the laws of the State of Delaware with its principal place of business in Lincolnshire, Illinois. (D.I. 1 at P 6) Apotex is the United States marketing and sales affiliate for TorPharm. (Id.) Plaintiff Apotex, Inc. is incorporated under the laws of Canada with its principal place of business in Weston, Ontario, Canada. (Id. at P 7) Defendant Pfizer Inc. is organized under the laws of the State of Delaware with its principal place of business in New York, New York. (Id. at P 9) Defendant Warner-Lambert LLC is a limited liability company organized under the laws of the State of Delaware with its principal place of business in Morris Plains, New Jersey. n1 (D.I. 1 at P 10)

n1 As of June 19, 2000, Warner-Lambert Company became a wholly owned subsidiary of defendant Pfizer Inc.. Warner-Lambert Company subsequently became Warner-Lambert LLC. (Id. at P 10)

[*3]

On January 8, 2004 and April 1, 2004, defendants filed motions to dismiss the complaint and the amended complaint, respectively, for lack of subject matter jurisdiction pursuant to *Fed. R. Civ. P. 12(b)(1)*. (D.I. 8, 20) These motions are presently before the court. For the reasons to follow, the court grants both motions.

II. BACKGROUND

A. Regulatory Approval for Brand Drugs

Under the *Federal Food, Drug, and Cosmetic Act* ("FFDCA"), an innovator pharmaceutical company ("innovator") who seeks to manufacture a new brand drug is required to file a new drug application ("NDA") with the Federal Food and Drug Administration ("FDA"). *21 U.S.C. § 355(a)*. Submitting an NDA is frequently a time-intensive and costly process because, among other things, the NDA must contain detailed clinical studies of the brand drug's safety and efficacy. The NDA also must include a list of patents which claim the brand drug:

The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such **[*4]** drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug... . Upon approval of the application, the Secretary shall publish information submitted under [this section].

21 U.S.C. § 355(b)(1). If the FDA approves an NDA, then it publishes, or "lists," information about the brand drug and patents covering the brand drug's approved aspects in a publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." Id.

B. Regulatory Approval for Generic Drugs

Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at *21 U.S.C. § § 355, 360cc* and *35 U.S.C. § § 156, 271, 282*, n2 a generic drug manufacturer ("generic") who seeks approval to market a generic version of a previously approved brand drug may submit an abbreviated new drug application ("ANDA") to the FDA. n3 *21 U.S.C. § 355(j)*. In the ANDA, a generic may rely on the safety and efficacy **[*5]** studies previously submitted to the FDA in the innovator's NDA by showing the generic drug's bioequivalence with the previously approved brand drug. *21 U.S.C. § 355(j)(2)(A)*. The generic also must "certify" whether the generic drug would infringe the patent(s) listed in the Orange Book for the brand drug. *21 U.S.C. § 355(j) (2) (A) (vii)*. To satisfy this requirement, a generic may make one of four possible certifications for each patent claiming either the listed brand drug or the use of the listed brand drug: (I) that no patent information on the brand drug has been submitted to the FDA; (II) that the listed patent has expired; (III) that the listed patent will expire on a stated date; or (IV) that the listed patent is invalid or will not be infringed by the generic product. *21 U.S.C. § 355(j) (2) (A) (vii) (I)-(IV)*. These options are designated as paragraph I, II, III, and IV certifications, respectively.

n2 The Drug Price Competition and Patent Term Restoration Act of 1984 is more commonly known as the "*Hatch-Waxman Act*." It amended various provisions of the FFDCA and Title 35 of the United States Code relating to patents. Title 1 of the Act was intended to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." *Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001)* (citing H.R. Rep. No. 98-857, pt. 1 at 14 (1984)). **[*6]**

n3 A generic does not commit an act of infringement in submitting an ANDA. *35 U.S.C. § 271 (e)(1)*("It shall not be an act of infringement to make, use, offer to sell, or sell ... a patented invention ... solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.").

With a paragraph I or II certification, the FDA may grant approval as soon as it is satisfied that the product is safe and effective. *21 U.S.C. § 355(j) (5) (B) (i)*. Under a paragraph III certification, the FDA may approve the ANDA as soon as the patent on the brand drug expires. *21 U.S.C. 355(j)(5)(B)(ii)*. If the generic enters paragraph III certifications for more than one patent, then the FDA may not grant approval until the last patent expires. Filing an ANDA with a paragraph IV certification presents a more unique situation; it is considered to be a

"technical" or "artificial" act of infringement. *35 U.S.C. § 271(e)(2)(A)*("It shall be an **[*7]** act of infringement to submit an application under *section 505(j)* of the [FFDCA] or described in *section 505(b) (2)* of such Act for a drug claimed in a patent or the use of which is claimed in a patent."); see *Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678, 110 L. Ed. 2d 605, 110 S. Ct. 2683 (1990)*("An act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by *§ 271 (e) (2)* - the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent."). Consequently, the ANDA applicant must explain why a generic version of the previously approved brand drug would not infringe the patent covering the previously approved brand drug or why such patent is invalid. *21 U.S.C. § 355 (j) (2) (B) (i)*. In response, the patent holder has the option of filing a patent infringement action within forty-five days after receiving such notice. *21 U.S.C. § 355(j)* **[*8]** *(5) (B) (iii)*. During this window, the generic may not file a declaratory judgment action based upon the filing of the ANDA. Id. If the patent holder fails to bring suit, then the FDA may approve the ANDA. Id. However, if the patent holder elects to bring suit, then the effective date of any FDA approval is delayed for either thirty months or until a court rules that the patent is invalid or not infringed, whichever occurs first. Id.

The first generic to file an ANDA containing a paragraph IV certification is known as a "first filer" and is eligible for a 180-day exclusivity period. This means that the first filer is entitled to have the sole generic version of the brand drug on the market for the first 180-days following the earlier of: (1) the date of the first commercial marketing of the generic drug by the first filer; or (2) a court decision of noninfringement or invalidity by any ANDA applicant in any action. *21 U.S.C. § 355(j) (5) (B) (iv)*. Any subsequent ANDA filer must wait until the expiration of this 180-day exclusivity period before the FDA will approve its ANDA. n4

> N4 If the first filer does not opt to commercially market its generic drug, then subsequent ANDA filers may trigger the 180-day exclusivity period by obtaining a court decision of noninfringement or invalidity.

[*9]

B. *The Medicare Act*

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457-60 (the "Medicare Act"). (D.I. 18 at P 48) Title XI of the Act, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA. (Id.) In particular, the Medicare Act amended *21 U.S.C. § 355(j) (5) (C) (i) (I) (2)* to provide that a generic who has filed a paragraph IV certification may bring a declaratory judgment action against the patent holder and/or holder of the NDA if: (1) the forty-five day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the holder of the NDA brought an action for patent infringement within the forty-five day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the ANDA. The Medicare Act also amended *21 U.S.C. § 355(j)(5)(C)(i)(II)* to provide that if the above three conditions are satisfied, then

> the applicant ... may, in accordance with *section 2201* of title 28, United States **[*10]** Code, bring a civil action under such section against the [patent] owner or holder [of the NDA] ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

The Medicare Act likewise added a new provision to *35 U.S.C. § 271(e)*, the section of the patent code relevant to infringement actions. This provision provides that if: (1) a generic makes a paragraph IV certification; and (2) the patent holder or holder of the NDA fails to sue the generic for patent infringement within the forty-five day window after receiving notice; then (3) "the courts of the United States shall, **to the extent consistent with the Constitution,** have subject matter jurisdiction in any action brought by such person under *section 2201* of title 28 for a declaratory judgment that such patent is invalid or not infringed." *35 U.S.C. § 271 (e) (5)* (emphasis added).

C. The Brand Drug Product

Accupril(R) is the brand name for *quinapril hydrochloride*. The FDA has approved Accupril(R) for the treatment of hypertension and for the management of heart failure. (D.I. 21 at P 4) Accupril(R) **[*11]** has been on the market in the United States since 1991. (Id.) In accordance with *21 U.S.C. § 355(b) (1)*, Pfizer listed the numbers and the expiration dates for the patents covering either Accupril(R) tablets or a method of using those tables with the FDA. (Id.) The FDA, in turn, published this information in the Orange Book. (Id.) The

'450 patent is one of the patents found in the Orange Book; it expires on February 24, 2007. (Id.)

D. The First Filer

At a date prior to January 15, 1999, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with paragraph IV certification directed to *quinapril hydrochloride.* (D.I. 22 at P 2) Teva asserted that the '450 patent is invalid. n5 On January 15, 1999, Teva notified defendant Warner-Lambert of this filing. (Id.) Within forty-five days thereafter, defendant Warner-Lambert filed an action against Teva for infringement of the '450 patent in the United States District Court for the District of New Jersey. (Id. at P 4; D.I. 26 at 11) On October 2, 2003, the District of New Jersey held that Teva infringes the '450 patent and granted summary judgment in favor of Pfizer on this ground. See **[*12]** *Warner-Lambert Co. v. Teva Pharms. USA, 289 F. Supp. 2d 515, 545 (D. N.J. 2003)*. n6 The parties have yet to litigate the issues of validity and enforceability. (D.I. 22 at P 5)

n5 The FDA approved Teva's ANDA on May 30, 2003. (D.I. 21 at 7)

n6 After receiving this favorable decision, defendants issued a press release commenting on the ruling. Defendants' senior vice president and general counsel stated: "[Defendants] [are] pleased with the court's summary judgment decision because it affirms positions the company has maintained with respect to the Accupril(R) patent from the very beginning of the litigation ... [Defendants] will continue aggressively to defend challenges to its intellectual property." (D.I. 21, ex. D)

As the first filer, Teva is entitled to a 180-day period of generic exclusivity from the earlier of: (1) the date it first commercially markets generic *quinapril hydrochloride;* or (2) the date of a court decision declaring the '450 patent invalid. See *21 U.S.C. § 355* **[*13]** *(j)(5)(B)(iv)(I), (II)*. To date, neither event has occurred. If Teva prevails in its litigation against Warner-Lambert and the District of New Jersey declares the '450 patent invalid, then the clock will start running on Teva's 180-day exclusivity period. Other generics who receive FDA approval will be able to begin marketing their generic versions of *quinapril hydrochloride* upon expiration of Teva's period of exclusivity.

E. Plaintiffs' ANDA

On September 13, 2001, plaintiffs filed an ANDA seeking approval to market its own generic version of *quinapril hydrochloride.* (D.I. 18 at P 62) Plaintiffs entered a paragraph IV certification with respect to the '450 patent. (Id. at P 64) Around November 15, 2001, plaintiffs notified defendants about the ANDA filing and the paragraph IV certification pursuant to *21 U.S.C. 355(j)(2)(B)(iv)*. (Id. at P 67) Defendants did not file a patent infringement action asserting the '450 patent against plaintiffs within forty-five days of receiving this notice. (D.I. 22 at P 6) On February 3, 2004, plaintiffs sent a letter to defendants offering confidential access to their ANDA. (D.I. 18 at P 69; D.I. 21, ex. **[*14]** G)

F. Other ANDAs Directed to *Quinapril Hydrochloride*

Besides Teva and the plaintiffs at bar, eight other generics have filed ANDAs seeking approval to market generic *quinapril hydrochloride* between January 2001 and May 2003. n7 These generics include: (1) Geneva Pharmaceuticals, Inc; (2) Andrx Pharmaceuticals, Inc.; (3) Par Pharmaceuticals, Inc.; (4) Ivax Pharmaceuticals, Inc.; (5) Mutual Pharmaceutical Company, Inc.; (6) Ranbaxy Pharmaceuticals Inc.; (7) Amide Pharmaceutical, Inc.; and (8) Mylan Pharmaceuticals Inc.. (D.I. 22 at P 7) Pfizer has not initiated litigation against any of these eight companies in connection with their ANDAs. (Id.)

n7 Though not specifically stated by the parties, the court presumes that each of these generics included paragraph IV certifications in their ANDA filings based upon the parties' representations about these filings.

III. STANDARD OF REVIEW

"Federal courts are courts of limited jurisdiction. They possess only that power authorized by the **[*15]** Constitution and statute ... It is to be presumed that a cause lies outside this limited jurisdiction and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. Of Am., 511 U.S. 375, 377, 128 L. Ed. 2d 391, 114 S. Ct. 1673 (1994)*(citations omitted). A subject matter jurisdiction attack under *Fed. R. Civ. Pro. 12(b)(1)*, therefore, challenges the court's jurisdiction to address the merits of the complaint. See *Lieberman v. Delaware, 2001 U.S. Dist. LEXIS 13624, 2001 WL 1000936, at *1 (D. Del. 2001)*. A party may raise the lack of subject matter jurisdiction at any time; it cannot be waived. *Fed. R. Civ. P. 12(h)(3)*. In fact, the court is obliged to address the issue on its own motion, if not raised by the parties. See *Neiderhiser v. Berwick, 840 F.2d 213, 216 (3d Cir. 1988)*. Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of

proving its existence. See *Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc., 227 F.3d 62, 69 (3d Cir. 2000)*.

Under *Rule 12(b)(1)*, the court's **[*16]** jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *Mortensen v. First Fed. Sav. & Loan, 549 F.2d 884, 891 (3d Cir. 1977)*. Under a facial challenge, the court must accept as true the allegations contained in the complaint. See 2 James W. Moore, Moore's Federal Practice § 12.30 [4] (3d ed. 1997). Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or ... is wholly insubstantial and frivolous.'" *Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1408-1409 (3d Cir. 1991)* (quoting *Bell v. Hood, 327 U.S. 678, 682, 90 L. Ed. 939, 66 S. Ct. 773 (1946)*).

Under a factual attack, however, the court is not "confined to allegations in the ... complaint, but [may] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States, 36 V.I. 392, 115 F.3d 176, 179 (3d Cir. 1997)*; see also *Mortensen, 549 F.2d at 891-892*. "No presumptive truthfulness **[*17]** attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group, 227 F.3d at 69* (quoting *Mortensen, 549 F.2d at 891*). Because defendants did not answer either plaintiffs' original complaint or their amended complaint, the court shall treat the instant subject matter jurisdiction challenge as a facial attack.

IV. DISCUSSION

A. The Legal Standard for Declaratory Judgment

The Declaratory Judgment Act states in pertinent part:

> In a case of actual controversy within its jurisdiction, ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

28 U.S.C. § 2201(a). Under this act, a court may declare the rights and other legal relations of any interested party only where there exists an "actual **[*18]** controversy." *Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999)*. This requirement effectuates Article III of the Constitution, which authorizes the federal judiciary to hear justiciable cases and controversies. n8 See *EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996)*.

> n8 The Supreme Court has held that Article III is satisfied where there is: (1) an actual or imminent injury-in-fact; (2) that is fairly traceable to the defendant; and (3) is redressible by a favorable decision. *Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-561, 119 L. Ed. 2d 351, 112 S. Ct. 2130 (1992)*.

To guide the case-or-controversy analysis in patent-based declaratory judgment suits, the Federal Circuit has developed a two-part test. "For actual controversy to exist, 'there must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit; and **[*19]** (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.'" *Amana, 172 F.3d at 855* (quoting *BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993)*). The burden is on the declaratory judgment plaintiff "to establish that jurisdiction over its declaratory judgment action existed at, and has continued since, the time the complaint was filed." *Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575 (Fed. Cir. 1986)*. "Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." *EMC Corp, 89 F.3d at 810*.

The first prong looks to the patent holder's conduct. *BP Chems. Ltd., 4 F.3d at 978*. If a defendant expressly charges that a plaintiff's current activity constitutes infringement, then there is an actual controversy. *Arrowhead Indus. Water v. Ecolochem, 846 F.2d 731, 736 (Fed. Cir. 1988)*. In light of the subtleties in lawyer language, however, courts have not **[*20]** required an express infringement charge. Id. (citing *Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 956 (Fed. Cir. 1987)*). When the defendant's conduct, including its statements, falls short of an express charge, the court must consider the "totality of the circumstances" in determining whether the defendant's conduct meets the first prong of the test. *Arrowhead, 846 F.2d at 736*. Thus, the declaratory judgment plaintiff must demonstrate "conduct that rises to a level sufficient

to indicate an intent [of the patent holder] to enforce its patent, i.e., to initiate an infringement action." *EMC Corp, 89 F.3d at 811* (citations omitted). Subjective impressions of the declaratory judgment plaintiff, however, are insufficient to satisfy the requirement. The court must find objective facts considering the totality of the circumstances at the time the complaint was filed. *Arrowhead, 846 F.2d at 736.*

The second prong looks to the potential infringer's conduct. *BP Chems. Ltd., 4 F.3d at 978.* The potential infringer must be engaged in an actual making, selling, or using activity subject to **[*21]** an infringement charge or must have made meaningful preparation for such activity. This prong insures that the declaratory judgment plaintiff has a "true interest to be protected" and prevents such plaintiff from seeking an advisory opinion on potential liability for initiating some future activity. *Arrowhead, 846 F.2d at 736.*

B. Defendants' Motion to Dismiss

1. Subject Matter Jurisdiction Pursuant to the Medicare Act

Plaintiffs argue that they are not required to satisfy the reasonable apprehension of suit requirement to confer subject matter jurisdiction pursuant to the amendments made to *21 U.S.C. § 355(j)(5)(C)(i)(II)* and *35 U.S.C. § 271(e)(5)* by the Medicare Act. (D.I. 26 at 14) Plaintiffs claim that they need only satisfy the case or controversy requirement of Article III of the Constitution. In this regard, plaintiffs contend that they have been directly injured by defendants because they cannot enter the *quinapril hydrochloride* market with their generic product until after the '450 patent expires due to the "bottleneck" that defendants created by engaging in litigation against Teva. n9 Plaintiffs maintain **[*22]** that a declaratory judgment in their favor will redress this injury as they will be able to market their generic version of *quinapril hydrochloride.* Accordingly, plaintiffs aver that the court has subject matter jurisdiction over the instant dispute.

> n9 Recall that pursuant to *21 U.S.C. 355(j)(5)(B)(iv)*, the FDA cannot approve plaintiffs' ANDA until 180 days after Teva enters the market with its generic *quinapril hydrochloride* or until a favorable court decision on the '450 patent, whichever is earlier. Plaintiffs claim that Teva will not enter the market because the District of New Jersey found that its generic version of *quinapril hydrochloride* infringed the '450 patent. Plaintiffs also allege that defendants have delayed filing suit against them or any of the other subsequent ANDA filers to avoid triggering a court decision that potentially may find the '450 patent not infringed or invalid.

The court does not read the plain language of either *21 U.S.C. § 355* **[*23]** *(j)(5)(C)(i)(II)* or *35 U.S.C. § 271(e)(5)* as eliminating the Federal Circuit's two-part test. Rather, the plain language of *21 U.S.C. § 355(j)(5)(C)(i)(II)* requires a generic to satisfy three prerequisites before lodging a declaratory judgment action against a patent holder; this provision does not in any way address subject matter jurisdiction. The plain language of *35 U.S.C. § 271(e)(5)*, on the other hand, reaches the issue of subject matter jurisdiction. It requires courts to exercise subject matter jurisdiction in a patent-related declaratory judgment action "consistent with the Constitution." The court interprets this language to mean that a generic must satisfy the case and controversy requirement set forth in Article III. Given that the Federal Circuit established its two-part test to guide the case-or-controversy analysis in conformity with Article III, the court finds that this test is "consistent with the Constitution" and applicable to the litigation at bar.

The court observes that the legislative history for the Medicare Act substantiates this interpretation. Congress specifically contemplated a continuation **[*24]** of the constitutional standard for subject matter jurisdiction, including the reasonable apprehension requirement. According to the House of Representatives conference report,

> the conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effect to delay infringement litigation between generic drug manufacturers and pioneer drug companies. **The conferees expect courts to apply the 'reasonable apprehension' test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.** Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction. The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act. In determining whether a reasonable

> apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought **[*25]** an infringement suit within the [forty-five] days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108-391, at 836 (2003)(citations omitted)(emphasis added). Taking this explanation together with the Federal Circuit's plain language of the Medicare Act, the court concludes that the two-part test remains as the standard for determining whether a district court has subject matter jurisdiction over a patent-based declaratory judgment action.

Turning to the facts at bar, plaintiffs were not required to comply with the three prerequisites set forth in *21 U.S.C. § 355(j)(5) (C) (i)(II)* because they filed their original complaint on October 29, 2003, approximately one month prior to the enactment of the Medicare Act on December 8, 2003. Nevertheless, the Medicare Act applies to all proceedings pending on or after December 8, 2003. As such, defendants focus on plaintiffs' amended complaint, which was filed on February 23, 2004, nearly **[*26]** three months after the Medicare Act became effective. To this end, defendants argue that plaintiffs filed their amended complaint only twenty days after offering defendants confidential access to their ANDA, well within the forty-five day period.

At the outset, the court observes that defendants confuse the prerequisites. The Medicare Act states that a declaratory judgment action may not be brought unless: (1) the forty-five day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor holder of the NDA brought an action for infringement of the patent within the forty-five day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the ANDA. The forty-five day window, therefore, relates to notice of the ANDA filing containing the paragraph IV certification, not notice of the complaint or, in the case at bar, the amended complaint. Additionally, compliance with the Medicare Act as of the date of the amended complaint is of no import; the Medicare Act seeks to ensure that a patent holder has full opportunity to consider an ANDA and decide whether to file an infringement action prior **[*27]** to being forced to stand in defense in a declaratory judgment action. This consideration occurs with the filing of an original complaint, not as of the filing of an amended complaint in a suit already in progress. Accordingly, the court declines to dismiss the instant litigation on procedural grounds.

2. Subject Matter Jurisdiction Under the Federal Circuit's Two-Part Test n10

> n10 The parties dispute only the first prong of this test, to wit, whether plaintiffs were in reasonable apprehension of an infringement suit as of October 29, 2003, the date of plaintiffs' original complaint. The court, therefore, confines its analysis to this question. For sake of clarity, the court observes that plaintiffs satisfied the second prong of the two-part test, i.e., activity which could constitute infringement, by filing the ANDA. See *35 U.S.C. § 271(e)(2)*; see also *infra* Section II, A.

Plaintiffs argue that they were under a reasonable apprehension of suit at the time they filed their **[*28]** complaint based upon various actions by defendants, including the following: (1) listing the '450 patent in the Orange Book n11 (D.I. 18 at PP 27, 89); (2) failing to state that plaintiffs' generic version of *quinapril hydrochloride* does not infringe the '450 patent or to provide plaintiffs with a covenant not to sue (id. at P 89); (3) initiating an infringement lawsuit against Teva regarding the *'450 patent (*id. at PP 80, 81); (4) stating in a press release "that it will continue to aggressively defend challenges to its intellectual property" (id. at PP 79, 89; D.I. 21, ex. D); and (5) initiating a lawsuit against plaintiffs over a different product (Neurotin(R)), thereby showing a "pattern of aggressively enforcing its patents" against "the generic pharmaceutical industry generally." (Id. at PP 72-78, 89)

> n11 Plaintiffs argue that defendants implied that an infringement action could be brought against any generic who seeks ANDA approval for a generic version of *quinapril hydrochloride* by listing the '450 patent in the Orange Book.

[*29]

Before delving into the details of plaintiffs' arguments, the court recognizes that it is often difficult to identify whether a reasonable apprehension of suit exists. This question entails a balance, similar to the balance that the Hatch-Waxman Act struck between innovators and generics. On the one hand, a patent owner should not be dragged into court when it has not engaged in threatening or aggressive acts simply because it chooses to inform potential infringers of its patent rights. In the

case of the pharmaceutical industry, an innovator has invested a tremendous amount of research effort, dollars, and time into developing and marketing a brand drug. Such innovators also have expended considerable resources in establishing a patent portfolio to protect said brand drug. The court respects both the innovator's efforts and legitimate patent rights and does not easily dismiss these investments. On the other hand, however, the Declaratory Judgment Act was enacted to prevent patent owners from using "guerrilla-like" tactics and attempting "extrajudicial patent enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with **[*30]** uncertainty and insecurity." *Arrowhead, 846 F.2d at 735*. As well, the court is mindful that a generic should be entitled to market its generic version of a brand drug if a product does not infringe the patent listed in the Orange Book for the brand drug or said patent is invalid. In such situations, the court appreciates that a declaratory judgment action may be the only means for a generic to reach the market given the possibility for a so-called "bottleneck."

With this background in mind, the court turns to consider plaintiffs' contentions concerning the first prong of the two-part test. Plaintiffs argue that a generic, in general, is placed in a position of reasonable apprehension of litigation when it submits an ANDA because a patent holder may file a patent infringement action against it. n12 In asserting this position, plaintiffs reference the concurrence from Judge Gajarsa in *Minnesota Mining & Mfg. Co. v. Barr Labs., Inc., 289 F.3d 775 (Fed. Cir. 2002)*. Judge Gajarsa opined that

> filing an NDA application meets prong one of the declaratory judgment case or controversy requirement, because filing the application requires the patentee **[*31]** to maintain that an infringement suit could 'reasonably be asserted' against one who 'engaged in the manufacture, use or sale of the drug.' This is 'conduct giving rise to a reasonable apprehension on the plaintiff's part that it will face an infringement suit or the threat of one.'

Id. at 791 (citations omitted). n13

> n12 Recall that in listing a patent in the Orange Book, a patent holder represents that a claim for infringement "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of the drug. See *21 U.S.C. § 355(b)(1)*.
>
> n13 Similarly, the D.C. Circuit appears to share this view, stating that
>
> > the Federal Circuit has had no occasion to decide whether there is a 'controversy of sufficient immediacy and reality' to support a declaratory judgment action, ... when the plaintiff requires a judgment under *section 355(j)(5)(B)* in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.
>
> *Mova Pharm. Corp. v. Shalala, 329 U.S. App. D.C. 341, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998)*.

[*32]

Judge Gajarsa's reasoning addresses the practical difficulties facing a generic in plaintiffs' situation, i.e., a generic who does not face a "reasonable apprehension of suit" but who needs a judicial determination in order to get to market. Nevertheless, absent binding precedent or further edification through legislation, the court declines to extend the well established principles governing declaratory judgment actions to cover the admittedly frustrating position occupied by plaintiffs at bar. In the first instance, defendants were required by statute to list the '450 patent in the Orange Book. In light of this obligation, the court is not convinced that defendants intended to communicate an intent to sue each and every generic who opts to file an ANDA for *quinapril hydrochloride,* contrary to plaintiffs' suggestion. The evidence of record, in fact, shows an opposite intention. To date, defendants have asserted the '450 patent only against Teva, despite at least eight other generics having filed ANDAs for *quinapril hydrochloride* with paragraph IV certifications. Additionally, our sister courts, when confronted with virtually identical facts to those at bar, have found that **[*33]** the act of listing a patent in the Orange Book does not create an "actual controversy." See *Mutual Pharm. v. Pfizer, 307 F. Supp.2d 88 (D. D.C. 2004)*; *Dr. Reddys Labs., Ltd. v. Pfizer Inc., 2003*

U.S. Dist. LEXIS 24351, 2004 WL 596106 (D. N.J. 2003); *Teva Pharms. USA, Inc. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 21940, 69 U.S.P.Q.2d 1791 (D. Mass. 2003)*. Indeed, the District of Massachusetts has noted that "[a] blanket reference to this effect would cover every patent holder who listed a patent, thereby eliminating the second prong of the test. A patent holder may have reasons to sue for infringement, and all things depending, reasons not to sue." *2003 U.S. Dist. LEXIS 21940, [WL] at *13*. The court, consequently, concludes that the mere listing of a patent in the Orange Book does not give plaintiffs reason to fear suit.

Plaintiffs also point out that defendants failed to state that plaintiffs' generic version of *quinapril hydrochloride* does not infringe the '450 patent and failed to provide them with a covenant not to sue. While the Federal Circuit previously has acknowledged that a patent holder's failure to give such an assurance is relevant to a court's jurisdictional inquiry, *BP Chems. Ltd, 4 F.3d at 980,* **[*34]** plaintiffs fail to cite evidence to demonstrate that they requested either an assurance or a covenant not to sue. Moreover, even if plaintiffs made such requests, defendants are not required under the Hatch-Waxman Act to give either an assurance or a covenant not to sue. Thus, the court declines to construe defendants' silence as conduct sufficient to suggest an intention to sue.

Plaintiffs likewise maintain that defendants' litigation history establishes a reasonable apprehension of suit. In this regard, plaintiffs call attention to fact that defendants: (1) are engaged in an ongoing infringement action against Teva regarding the '450 patent; (2) have been involved in suits against plaintiffs and at least eight other ANDA filers over Neurotin(R) for the past five years; and (3) are actively pursuing other infringement actions against various generics who sought to market generic versions of their brand drugs, including Zoloft(R), Celebrex(R), Lipitor(R), Norvasc(R), Procardia XL(R), Glucotrol XL(R), and Xalatan(R). As to plaintiffs' litigation involving the '450 patent, defendants have not sued any of the subsequent eight ANDA filers, four of whom filed ANDAs prior to plaintiffs. **[*35]** n14 Contrary to plaintiffs' characterization of this fact as "meaningless," the court finds it to be persuasive evidence that defendants are not engaged in a pattern of widespread litigation aimed at enforcing the '450 patent against all generics interested in marketing generic *quinapril hydrochloride*. As such, the court declines to conclude that defendants' litigation efforts with respect to Teva translate into an intent to enforce the '450 patent against plaintiffs.

n14 Geneva Pharmaceuticals, Andrx Pharmaceuticals, Par Pharmaceuticals, Inc., and Ivax Pharmaceuticals, Inc. filed ANDAs seeking approval to market generic *quinapril hydrochloride* on January 9, 2001, January 25, 2001, June 1, 2001, and July 20, 2001, respectively. Plaintiffs did not file their ANDA until September 13, 2001.

The court is equally unpersuaded that defendants' Neurotin(R) litigation created a reasonable apprehension of suit. In *Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed. Cir. 1987),* **[*36]** the Federal Circuit acknowledged that a history of adverse legal interests bears upon the reasonable apprehension issue, even if the prior litigation did not involve the same patents implicated in the declaratory judgment suit. Nonetheless, the court observes that the link between the parties' adverse legal interests in *Goodyear* were much stronger than those at bar. In Goodyear, the defendant sued the plaintiff in state court over the same technology covered by the patents disputed in the declaratory judgment action. The Federal Circuit opined that, "by suing Goodyear in state court for the same technology as is now covered by the patents, [defendant] has engaged in a course of conduct that shows a willingness to protect that technology." *Id. at 956*. In contrast, defendants' Neurotin(R) litigation does not implicate the same technology as would be involved in a suit over Accupril(R). Therefore, the court finds that defendants' desire to protect their presence in the pain and seizure markets with Neurotin(R) is unrelated to their intentions as to the hypertension and heart failure markets with Accupril(R). While the parties' adverse interests remain a consideration, **[*37]** the court finds that the factual background in this case, unlike the factual background in *Goodyear,* is not such that plaintiffs had an objective reason to fear litigation.

Similarly, the court finds that defendants' litigation against third party generics, even when viewed in the aggregate with defendants' suit against Teva and their Neurotin(R) litigation, does not place plaintiffs in a reasonable apprehension of suit. (See D.I. 27, ex. B) Plaintiffs overdramatize the situation in stating "there is no end to the lengths that [defendants] will go to protect its branded monopolies through litigation." Plaintiffs' subjective beliefs do not amount to a threat or other action sufficient to prove the imminence of a lawsuit. In addition, that defendants enforced their patent rights against other generics with respect to Zoloft(R), Celebrex(R), Lipitor(R), Norvasc(R), Procardia XL(R), Glucotrol XL(R), and Xalatan(R) does not provide any indication of its intentions regarding the '450 patent and *quinapril hydrochloride*. To this end, the Federal Circuit

considers whether the parties have engaged in some form of communication about the patent in dispute when analyzing the reasonable **[*38]** apprehension question. n15

> n15 Notably, the Federal Circuit also has recognized that "if circumstances warrant, a reasonable apprehension may be found in the absence of any communication from defendant to plaintiff." *Arrowhead, 846 F.2d at 736*.

The Federal Circuit has cautioned:

> The test for finding a "controversy" for jurisdictional purposes is a pragmatic one and cannot turn on whether the parties use polite terms in dealing with one another or engage in more bellicose saber rattling. The need to look to substance rather than form is especially important in this area, because in many instances ... the parties are sensitive to the prospect of a declaratory judgment action and couch their exchanges in terms designed either to create or defeat declaratory judgment jurisdiction. In the end, the question is whether the relationship between the parties can be considered a "controversy," and that inquiry does not turn on whether the parties have used particular "magic words" in communicating **[*39]** with one another.

EMC Corp., 89 F.3d at 811-12. The Federal Circuit has found no apprehension of suit existed where the patent holder has made no contact with the declaratory judgment plaintiff. *West Interactive Corp. v. First Data Res., Inc., 972 F.2d 1295, 1297 (Fed. Cir. 1992)*. n16 In the case at bar, plaintiffs have not alleged any communication, either direct or indirect, from defendants concerning the '450 patent. The record also does not reveal any such communication. Moreover, the record does not show that defendants communicated with any third parties about plaintiffs or the '450 patent. As noted above, defendants have stood silent throughout the course of this litigation. The only interaction between the parties, in fact, occurred when plaintiffs initiated contact with defendants by: (1) notifying them of their ANDA with paragraph IV certification as required by *21 U.S.C. § 355 (j) (2) (B)*; and (2) sending them a letter offering confidential access to their ANDA in accordance with *21 U.S.C. § 355 (j) (5) (C) (i) (I) (2)*. Given these circumstances, plaintiffs cannot complain that they feared **[*40]** that defendants would sue them for patent infringement.

> n16 In contrast, the Federal Circuit has held the reasonable apprehension inquiry satisfied in certain situations where the defendant directly communicated with the plaintiff. See, e.g., *Sierra Applied Scis. Inc. v. Advanced Energy Indus., 363 F.3d 1361, 1374 (Fed. Cir. 2004)* (concluding that letters from defendant to plaintiff expressly charging plaintiff with patent infringement were sufficient to establish a reasonable apprehension); *EMC Corp., 89 F.3d at 812* (finding a letter from defendant to plaintiff referencing "'turning the matter over to'" plaintiff's litigation counsel '" for action'" and urging a "'preliminary business discussion,'" "'perhaps avoiding this matter escalating into a contentious legal activity[,]'" to be the "most telling evidence" of reasonable apprehension).

Finally, defendants' press release statement that they "will continue aggressively to defend challenges to [their] intellectual property" **[*41]** is not sufficient to instill a reasonable apprehension of suit. Defendants' statement, even though made in the context of discussing the infringement suit against Teva, is of a general nature, directed to their overall strategy of enforcing their patent rights against generic competition. It is not specifically directed against plaintiffs, nor is there any evidence suggesting that it was made with plaintiffs in mind. The Federal Circuit has held that a patent holder's statement that it intends to enforce its patent does not create a reasonable apprehension of suit. *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1054 (Fed. Cir. 1995)* (discussing *Shell Oil Co. v. Amoco Corp., 970 F.2d 885, 889 (Fed. Cir. 1992)*). Accordingly, the court concludes that, under the totality of the circumstances, defendants did not engage in conduct sufficient to give plaintiffs a reasonable apprehension of suit at the time they filed the complaint at bar. The court, therefore, grants defendants' motions to dismiss for lack of subject matter jurisdiction. n17

> n17 As noted above, the court is sympathetic to plaintiffs' situation. Plaintiffs must dwell within the frustrating Hatch-Waxman "bottleneck" (the expiration of Teva's 180-day period of exclusivity) before marketing their generic version of *quinapril* hydrochloride. The start of this exclusivity period presently,

however, remains unknown and will not be triggered until either: (1) Teva voluntarily markets its generic *quinapril hydrochloride,* which it is not likely to do given the District of New Jersey's finding of infringement; (2) the District of New Jersey decides the issues of validity and enforceability of the '450 patent; or (3) another court declares the '450 patent invalid. Thus, subsequent ANDA filers, like plaintiffs, are placed in a conundrum when attempting to market their generic versions of brand drugs under the current regulatory framework.

[*42]

V. CONCLUSION

For the reasons stated, the court grants defendants' motions to dismiss for lack of subject matter jurisdiction. An order shall issue.

ORDER

At Wilmington this 28th day of June, 2004, consistent with the opinion issued this same date;

IT IS ORDERED that defendants' motions to dismiss (D.I. 8, 20) are granted.

Sue L. Robinson

United States District Judge